

eRA Commons Working Group (CWG) Meeting Agenda

Meeting Details:

Tuesday, January 10, 2017

1:00-3:00 p.m.

Room: Lobby Level, Congressional A Ballroom

Hyatt Regency Washington

400 New Jersey Ave, NW

Washington, DC 20001

[Map and Directions](#)

[Floor Plan](#)

Agenda Items:

1. Forms Changes

Facilitators: Stefanie Harris and Megan Columbus

Clinical Trial Forms

- NIH is currently working on developing a new form that will capture detailed information on clinical trials as discrete elements, and combine clinical trial, human subject, and inclusion information from across the application into a single form.
- Information will be captured on a study by study level, similar to inclusion forms
- Human subject questions will be removed from other PHS forms, and the new human subjects form will replace the existing inclusion form.
- Aligning data elements with those that are captured in ClinicalTrials.gov, with end goal of supporting transfer of data between eRA systems and Clinical Trails.gov.
- Suggestion was made by a CWG member to think through the relationship of the studies to the sites.

The new form is a big undertaking, with big impact, especially on S2S development

- While the current implementation date that is out there is to use the new form by September 25, 2017, that is a huge stretch. Stay tuned.
- Hoping for OMB approval of the form by March.
- Working with Grants.gov for XML development to be able to provide to S2S developers the information as soon as possible

Terminology check: what does "Delayed Onset" mean to people?

Per NIH policy, Delayed Onset generally means that a study has not been developed and cannot be described in terms of human subjects' protections and inclusion. This does NOT apply to a study that can be described but will not start immediately.

- Is this the best terminology? Meeting participants did not find the term intuitive.
- Is "Indefinite Onset" better? Folks found it better, but not great.

Forms Transitions

- Implementing the new human subject form will move us to Forms E
- For form transitions, what is the most applicant friendly approach to making the new form version available?
 - Staggering availability of new form version based on FOA due date/activity code?
 - Posting the new form versions on all FOAs at once?
- For the transition for Forms C to D, we used the last due date as the reference to update application packages.
 - Due to the number of exception (aids date, continuous submission, grace period, etc.) this was difficult to manage
- Which is harder for applicants? 2 form sets available at the same time, or staggering the release of forms version?

- Group considered it to be most clear to have 2 versions with notifications of “on or after” a specified date to specify the package to use. It’s much less labor intensive for NIH to take this approach.

2. eRA Commons Update

Facilitator: Yuri Gorbach

Final RPPR

- Available and required as of Jan1, 2017
- Differences between Final RPPR (F-RPPR) and standard RPPR
 - Final RPPR must be submitted to agency to close out a project. Grant will be in Closeout at that point.
 - Interim RPPR must be submitted to close out a competitive segment.
 - Regular Annual RPPR is submitted to report on the yearly basis.
 - If you are in the process of filling out an Interim RPPR and the grant goes into closeout, system will automatically transfer data to Final RPPR (Accessible from Closeout) and remove the Interim RPPR link.
 - If you are the process of filling out Final RPPR and the grant comes out of closeout, Interim RPPR link will become available to Grantee on the next day. (We are working on more elegant solution in the future on how to reconcile IRPPR and FRPPR in such cases.)
 - Type 2 Applications
 - Complete F-RPPR as you normally would
 - If funded, the F-RPPR acts as an annual or interim RPPR
 - If not funded, F-RPPR remains the Final Research Performance Progress Report

Request: An info graph outlining the Type 2 application process with FRPPR would be helpful

- F-RPPR uses a new section, Outcomes
 - Should be written in plain language
 - Describe public impact
- How will NCE impact FRPPR?
- Can submission of the interim or Final RPPR be delegated?
 - Interim RPPR & Final RPPR have the same set of permissions as FPR, which is both can be initiated and submitted by either the PI or a SO
 - Make delegations of Interim and Final RPPR separate from Annual RPPR?
 - Why do we need a delegation for Final RPPR?
 - Reduce burden on central office
 - No critical information is required to get funded again
 - When delegating RPPR submission, allow choices to be annual, final, or both (We are working on this in the future)

3. Seeking Input on Revamp of Signing Official Status Screen

Facilitator: Yuri Gorbach

- Our initial thoughts
- Are there changes you would like to see?

New Signing Official Status Search Screen

- Working on new design to meet new UI standards
- Suggestions?
 - Get rid of budget dates!
 - Be able to export data to a spreadsheet
 - Adjust due dates not to fall on weekends and holidays (similar to submission policy)
 - Include on Personal Profile training/certification information
 - Human Subject, Good Clinical Practices, etc.
 - Then be able to run a report on that information
 - Who needs that training?
 - Check the FOA and Guide Notices
- Other ideas? Let us know by sending a note to Scarlett Gibb scarlett.gibb@nih.gov

4. eSubmission/ASSIST Update

Facilitator: Laurie Roman

Aspose – application image generation software

- Fully in place
- Still working through some small issues

New application warning concerning use of appendix

- Guide Notice [NOT-OD-16-129](#)
- Unless FOA specifies the use of the an appendix, don't add one (except in few instances allowed by policy)
- Double check FOA

Budget Forms

- New budget forms are ready. Will post FOAs for testing. No plan to use the new budget form until we repost for other reasons.

SBIR/STTR program renewed

- New forms are available but no timeline for release
- Will use current forms until FOAs specifically ask for/require new version

ASSIST changes

- New link from ASSIST to Status search screen for SOs in eRA Commons
 - Make it easier/quicker for SO reject an application
- New Multi-Employment Functionality
 - Senior Key Persons affiliated with multiple organizations will be able to select from their current employments
- New functionality with a locked form
- When a form is locked because it has been opened but someone else, the system displays the name of the person who has the form locked

Recommendation: add the ability for a form to be unlocked by someone else

- Time period? Locked idle time is being reviewed and tested for 45 minutes idle time
- New role ASSIST_ACCESS_MAINTAINER_ROLE
 - Only the Signing Official (SO) has the authority to provide this role to whomever they want to manage access to applications in ASSIST on behalf of the organization.
 - By providing this role, the SO is delegating the authority to manage access to all applications at the organization level, rather than application by application level.
 - Access Management within ASSIST for individual applications has not changed.

5. On screen application guide instructions

Facilitator: Laurie Roman

- Demo of our current thinking for ASSIST
- Discussion of making application guide available as a service for use by other systems

Links to demo videos (no audio)

Videos shown at the meeting can be viewed at:

- https://era.nih.gov/files/ASSIST/ASSIST_1_Field_Level_Help.mp4
- https://era.nih.gov/files/ASSIST/ASSIST_2_Component_Validation.mp4
- https://era.nih.gov/files/ASSIST/ASSIST_3_Required_Fields.mp4

Seeking feedback: How do you like the layout? What would you like different?

- As more features are developed, have a webinar to demo what is new, get feedback
- Possibly provide video of features ahead of time so people would have time to share and formulate comments/suggestions
- Rethink the Summary page not to show ALL the errors
- Reduce the clutter
- Do not list recurring errors (the same error across multiple forms/fields)
- Could the Help for error checks be provided as a service? Field level API Help?

6. General Discussion/Wrap-up

Facilitator: Megan Columbus

Next meeting Friday, May 12

Friday Meetings – is there a better way?

- Late Friday meetings make attendance difficult
 - travel limited
 - additional costs
- May start to look into conducting pre-webinar
 - Demo features in development
 - Discuss new development potentials
 - Discuss possible policy changes
- Then have 1 to 1½ hour face to face
 - Better interaction with face to face meetings, want to maintain that to some level

Next Meeting

Friday, May12, 2017

12:30 – 2:00

Room; TBA

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400 New Jersey Ave, NW

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